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EPA Plans New Peer Review To Address Industry Concerns Over IRIS

EPA officials say they are adding an additional peer review step at the start of its process for crafting its Integrated Risk Information System (IRIS) chemical risk assessments -- the latest in a series of new measures the agency is taking to improve its IRIS program and one long sought by industry before the agency's draft assessments are issued for review.

"We're . . . adding an early peer consultation step for some assessments before a draft [IRIS assessment] is written so we can have a fuller discussion" of the science, Becki Clark, acting director of EPA's National Center for Environmental Assessment, which oversees the IRIS program, told the National Academy of Sciences (NAS) Board on Environmental and Toxicological Studies (BEST) Jan. 25.

She added that the first of these consultations is under consideration for the summer of 2012, and would consider a toxicological issue regarding mouse lung tumors relevant to three ongoing IRIS assessments of ethylbenzene, naphthalene and styrene.

Industry representatives have long complained that EPA's IRIS assessments, often the basis for agency regulations and other decisions, are overly stringent and ignore data that suggests lower risks. As a result, groups like the American Chemistry Council have long pushed the agency to hold scientific meetings with stakeholders before they get too far along in assessing chemicals.

Since the release last spring of the NAS' review of EPA's draft assessment of formaldehyde risks, industry has used the recommendations to argue for delays and re-writes of major IRIS assessments including the ubiquitous contaminant dioxin. The NAS formaldehyde report was particularly notable because its authors devoted a chapter of recommendations to EPA's overall process and scientific approach for drafting the documents, beyond just the formaldehyde assessment.

EPA has already announced numerous changes intended to address the NAS formaldehyde report. Many seek to make IRIS documents more transparent and easier to read. During the Jan. 25 meeting at NAS, EPA officials reiterated several additional ideas for addressing the formaldehyde report's recommendations on their scientific approach to creating the IRIS documents, including the pre-draft scientific meetings and adopting a standardized weight of evidence framework to use in drafting the assessments.

EPA Plans Workshop

Vincent Coglian, acting IRIS director, said EPA will host a workshop to explore weight of evidence approaches later this year, during remarks at the Society for Risk Analysis annual meeting in Charleston, SC, in December.

Clark reiterated the agency's interest in the approach, telling the NAS the program is "moving toward a standardized weight of evidence characterization for all health effects" in future IRIS documents. She added that, "keeping the IRIS program strong is a priority for EPA."

One of the board members, consultant Gail Charnley, asked during the Jan. 25 meeting whether "there would be an advantage" if BEST convened the workshop. But Coglian disagreed, explaining that he is hoping to get the new framework in place "quickly." NAS reports often take 18 months or more to complete.

"We're still getting comments [on IRIS assessments] saying we're not doing this [weight of evidence assessment]," Coglian replied. "I'm hoping to have the workshop, review by [EPA's Science Advisory Board] and implement . . . I think we can do it by the agency within the year."

Additionally, Clark said that all new IRIS assessments will include a new 15-page preamble explaining the agency's approach to the IRIS assessment. Each preamble is "responsive to the [NAS] recommendations by describing methods and criteria used to develop the assessments" and will address five topics, according to slides Clark presented, including "identifying and selecting pertinent studies"; "evaluating the quality of individual studies"; "weighing the overall evidence for each effect"; "selecting studies for derivation of toxicity values" and "deriving toxicity values." -- Maria Hegstad (mhegstad@iwpnews.com)